UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION	**Civil Action No. 3:16-md-2738- MAS-RLS** **MDL No. 2738**

THIS DOCUMENT RELATES TO ALL CASES

THE PLAINTIFFS' STEERING COMMITTEE'S MEMORANDUM OF LAW IN RESPONSE AND OPPOSITION TO DEFENDANTS JOHNSON & JOHNSON AND LLT MANAGEMENT, LLC'S MOTION TO EXCLUDE THE OPINIONS OF DR. JOHN GODLESKI

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The Plaintiffs' Steering Committee ("PSC") submits this Memorandum of Law in response and opposition to *Defendants Johnson & Johnson and LLT Management, LLC's Motion to Exclude the Opinions of Dr. John Godleski* (ECF Doc. 33004-2) ("Motion"). For the foregoing reasons, this Court should deny Defendants' Motion.

I. INTRODUCTION

Dr. John Godleski is Plaintiffs' expert pathologist and analytical microscopist. He has been testifying in talc/ovarian cancer cases for more than ten years. Dr. Godleski's methodologies and opinions regarding talc and ovarian cancer have been allowed in *every* court in which they have been offered. His methodologies and opinions have been *Daubert* tested and *Daubert* approved. *See e.g. Berg v. Johnson & Johnson*, 940 F. Supp. 2d 983, 993 (D.S.D. 2013). Judge Karen E. Schreier of the United States District Court for the District of South Dakota's analysis and conclusion is instructive: "[A]fter a careful review of the record, the court concludes that Dr. Godleski's expert testimony is reliable." *Id*. The very same opinion Defendants again seek to exclude has been admitted at least 14 times to date, in courtrooms around the country, in *every trial in which Dr. Godleski has testified.*[1]

[1] Defendants begin their Memorandum by quoting the Court from the 2017 *Echeverria* trial but fail to disclose that the Court later reversed her decision and allowed Dr. Godleski's causation opinion. See *Echeverria v. Johnson & Johnson, et al*., No. BC628228, Aug. 3, 2017, Tr. at 2052:20-26 (Sup. Ct. CA, Los Angeles Cty.) ("Q. One last question, Doctor [Godleski]. Can it be stated to a reasonable degree of medical certainty that the presence of talc found in a woman's ovarian tissue can be contributory evidence for a causal link between the presence of talc and the

Dr. Godleski applies the very same methodology in this case that he used in the other cases, and he offers the exact same causation opinion. Moreover, Dr. Godleski's methodology in identifying talc, asbestos, or other particles in tissues has been published numerous times, including: McDonald SA, Fan Y, Welch WR, Cramer DW, Stearns RC, Sheedy, LJ, Katler, M, Godleski JJ. *Correlative polarizing light and scanning electron microscopy for the assessment of talc in pelvic region lymph nodes.* Ultrastructural Pathology 2019;43(1):13-27, attached as **Exhibit 2**; Campion A, Smith KJ, Fedulov AV, Gregory DZ, Fan Y, Godleski JJ. *Identification of Foreign Particles in Human Tissues Using Raman Microscopy*. Analytical Chemistry 2018 90 (14), 8362- 8369, attached as **Exhibit 3**; McDonald SA, Fan Y, Rogers RA, Godleski JJ. *Magnesium/silicon atomic weight percent ratio standards for the tissue identification of talc by scanning electron microscopy and energy dispersive X-ray analysis*. Ultrastructural Pathology, 2019; 43(6):248-260, attached as **Exhibit 4**.

Dr. Godleski's opinions are reliable, well-founded, and based on well-accepted scientific principles, making them admissible in the United States District Court of New Jersey, and elsewhere, pursuant to Rule 702.

Defendants demonstrate in their motion that they either do not understand, or did not accurately describe, Dr. Godleski's methodology for identifying talc in

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development of a woman's ovarian cancer? A. Yes."), attached as **Exhibit 1**.

tissue. Desperate to exclude Dr. Godleski's findings and opinions, they distort their "facts" and arguments to provide a basis to exclude him. A *proper* explanation of Dr. Godleski's methodology and findings, and the reasonable opinions derived therefrom, clearly demonstrates that his opinions satisfy the *Daubert* requirements and are admissible.

II. DR. GODLESKI'S QUALIFICATIONS AND METHODOLOGY

Dr. John Godleski's qualifications and expertise in anatomic pathology and analytical microscopy are impeccable. He is one of the most respected, credentialed experts in these fields. (*See* Dr. Godleski's Curriculum Vitae, attached as **Exhibit 5**). Since 1975, he has been a certified member of the American Board of Anatomic Pathology. (Exhibit 5 at p. 26). He currently serves as Professor *Emeritus* at Harvard Medical School and Harvard School of Public Health, where he has taught advanced pathology and analytical microscopy to countless medical students, residents, physicians, and scientists. (Exhibit 5 at p. 2). Before retiring, Dr. Godleski served for 37 years as the head of the Pulmonary Pathology Program at Brigham and Women's Hospital (now Mass General Brigham), one of Harvard's primary teaching hospitals. He has spent his career analyzing tissue samples and identifying foreign materials in tissue using light microscopy, scanning electron microscopy, and energy dispersive x-ray spectroscopy. And that is precisely what he was asked to do in these cases. Dr. Godleski was retained in these MDL

bellwether cases to carefully analyze the plaintiffs' gynecologic tissue, confirm the diagnosis of the treating pathologist, and determine whether there were any talc particles or other deleterious particles in the corpus of the tissue, as described in each of his reports. (*See* **Exhibit 6**, Dr. Godleski's Expert Report in *Gallardo*; **Exhibit 7**, Dr. Godleski's Expert Report in *Converse*; **Exhibit 8**, Dr. Godleski's Expert Report in *Rausa*; **Exhibit 9**, Dr. Godleski's Expert Report in *Judkins*; **Exhibit 10**, Dr. Godleski's Expert Report in *Newsome*.)

The pathology and microscopy methodologies used by Dr. Godleski are well established and are taught at Harvard Medical School and Harvard's School of Public Health, as well as other institutions around the world. They have been peer-reviewed and published over a hundred times. (Exhibit 5, at pp. 13-46). Furthermore, the pathologic and microscopic evidence offered by Dr. Godleski speaks for itself. Dr. Godleski unequivocally identified talc and asbestos in Plaintiffs' gynecologic tissue using state of the art scanning electron microscopy ("SEM") with energy dispersive x-ray spectroscopy ("EDX"), which uses objective computer-generated analytics to analyze the particles and fibers to determine their atomic composition. (Exhibits 6-10). This million-dollar instrument not only allows Dr. Godleski to visualize the morphologic and structural features of the individual particles and fibers and the biologic structures around them, but it also determines the atomic composition and elemental ratio of atoms in the particles. Talc has a

unique magnesium to silicon to oxygen ratio that distinguishes it from other minerals. The different varieties of asbestos also have unique elemental compositions that allow easy identification by SEM/EDX. In short, this well-recognized, multi-faceted analytical microscopy process results in the objectively unequivocal identification of talc and asbestos in tissue. And no court has ever ruled that Dr. Godleski's analytical methodologies were even the slightest bit unreliable or inconsistent with well-accepted scientific methods.

III. FACTUAL BACKGROUND

In each bellwether case where tissue was available (Rausa, Converse, Judkins, Newsome, and Gallardo), Dr. Godleski was asked to do the same thing – to review the Plaintiffs' surgical slides to confirm the hospital pathologist's diagnosis, make note of any relevant observations, and study the preserved blocks of Plaintiffs' gynecologic tissue for the presence of talc, asbestos, and other foreign materials. To confirm the diagnosis, Dr. Godleski used a routine light microscope (as the treating hospital pathologist did) to observe the malignant cells. Although Defendants like to point out that Dr. Godleski is a Board-certified pulmonary pathologist, Defendants do not challenge Dr. Godleski's training and experience in gynecologic pathology nor his ability to confirm Plaintiffs' diagnoses.

Once Dr. Godleski confirms the diagnosis, he then changes the light microscope lens to a polarizing lens. This allows him to observe any birefringent

particles or fibers present in the surgical slides in the same plane of focus as the tissue. (Exhibits 6-10). Birefringence is an optical property of talc and other magnesium silicates that causes them to stand out from the carbonaceous tissue background. This technique also allows the microscopist to observe with high resolution the anatomical structures on a cellular level that may be associated with or near the foreign materials. For example, see below Figure 2 from Dr. Godleski's expert report in *Gallardo*. (Exhibit 6, Gallardo Report, p. 3).

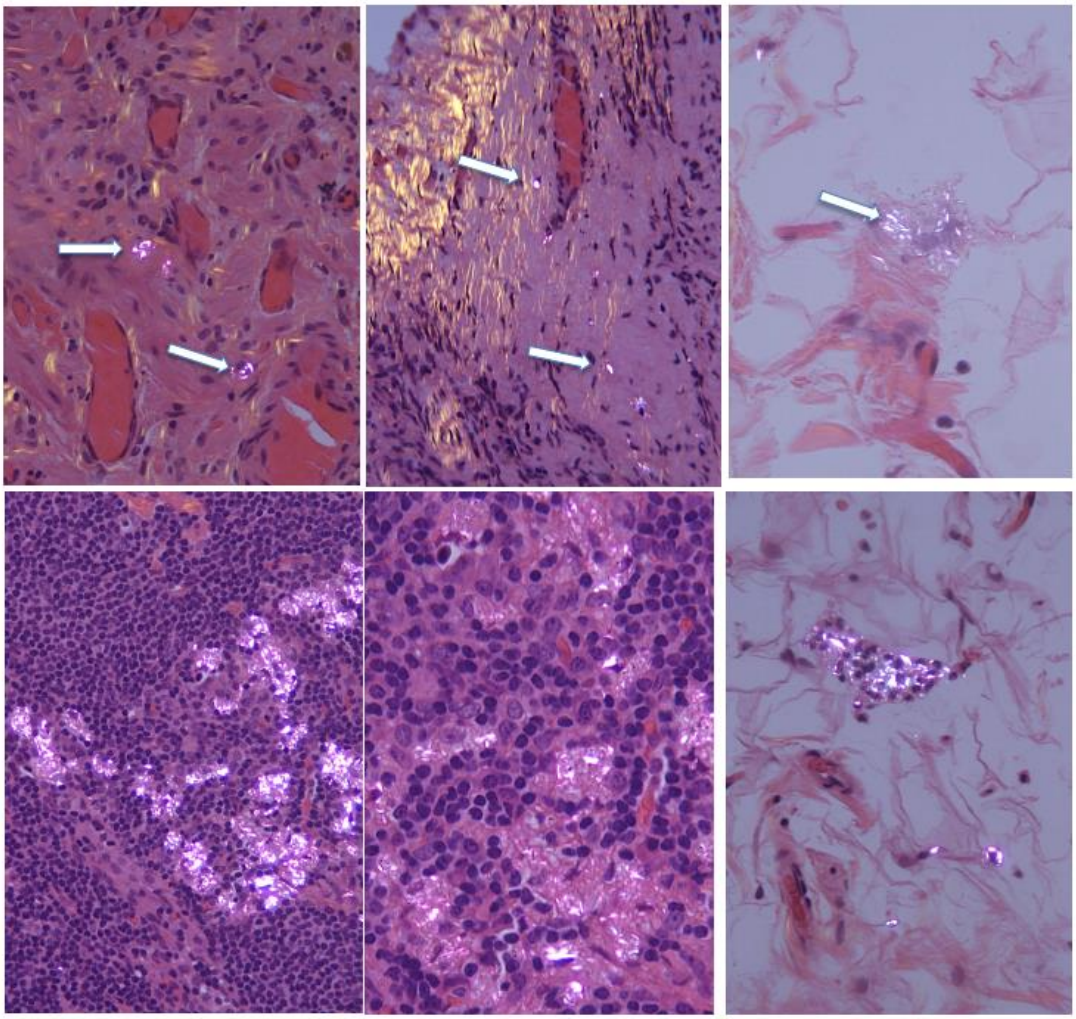
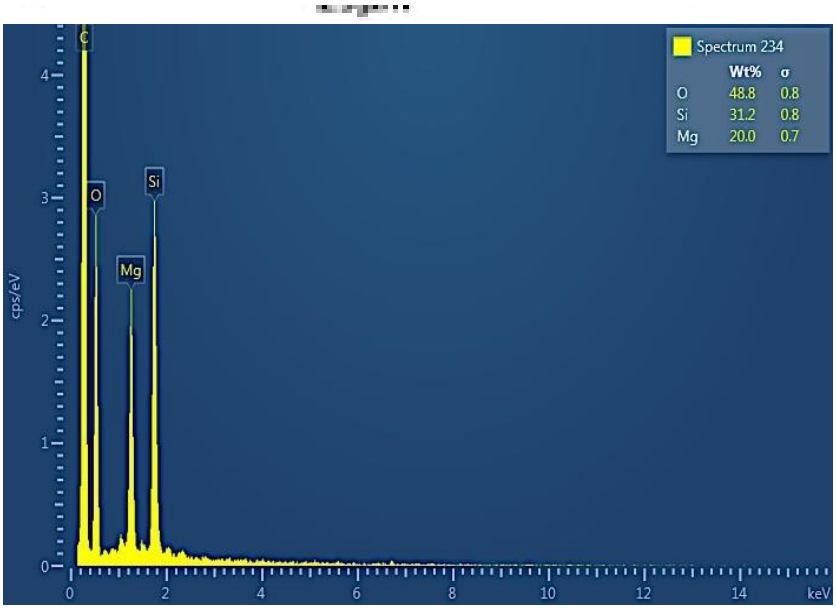


Figure 2. All images with polarized light microscopy. **Top Left.** High-power microscopic view of birefringent particles within cells (arrows) in the wall of the left fallopian tube. Original magnification 400X. **Top Center.** High power microscopic view of individual birefringent particles (arrows) within a fibrotic area of the right fallopian tube. Original magnification 400X. **Top Right.** High-power view of a cluster of birefringent particles (arrow) in a focus of chronic inflammation in the fat and soft tissue of the left gutter. Original magnification 400x. **Bottom Left.** Low power microscopic view of large numbers of birefringent particles in macrophages within a right external iliac lymph node. Original magnification 200X. **Bottom Center.** High power view of right iliac node showing many birefringent particles and fibers. Original magnification 400X. **Bottom Right.** Cluster of birefringent particles and fibers in a section of omentum. Also, scattered individual particles. Original magnification 400X. All images stained with Hematoxylin and Eosin.

Once Dr. Godleski has studied the surgical slides, he then requests appropriate tissue blocks from the hospital to study the material with scanning electron microscopy and energy dispersive x-ray spectroscopy ("SEM/EDX"). Defendants state incorrectly in their motion that Dr. Godleski studies the Plaintiffs' surgical slides with SEM. (Defendants' Memorandum, pp. 3-4). Dr. Godleski uses variable pressure SEM/EDX to study the tissue *blocks*, not slides, so as to visualize foreign materials *in situ* or in the actual tissue blocks. Variable pressure SEM allows the microscopist to peer below the surface of the tissue block to see particles and fibers at significant magnification within the corpus of the block, along with the surrounding tissue structures. The chosen particles and fibers are then analyzed *in situ* by the EDX instrument to determine atomic composition. As described above, the EDX software identifies particles as talc by recognizing and measuring the atomic ratio of the magnesium, silicon, and oxygen atoms of the particles. The same is done for other minerals including asbestos. These objective computer calculations are then recorded along with the particle's exact location. All of the SEM/EDX data

is provided to the defendants so they can verify Dr. Godleski's findings by SEM, but they never do. Despite the ease and availability of the tissue blocks and data, neither of Defendants' pathologists, Dr. Longacre nor Dr. Felix, have attempted to verify Dr. Godleski's findings in these cases, nor have they done so in any of the prior talcum powder cases in which they have offered opinions. Below is a sample SEM/EDX spectral analysis of a talc particle, again taken from Dr. Godleski's report in *Gallardo*. (Exhibit 6, Gallardo Report, p. 3).



It should be noted, this technique for identifying foreign material in tissue has been historically used by scientists for decades. Indeed, the EDX instrument and software was designed for this very purpose, and it is updated and recalibrated frequently to ensure accuracy. Furthermore, Dr. Godleski's findings and methodology for identifying talc and asbestos in tissue has been published numerous

times in respected, peer-reviewed scientific journals and textbooks, and he has lectured on the subject internationally for decades.[2] Tellingly, Defendants offer no SEM/EDX expert witness to refute Dr. Godleski's findings.

IV. LEGAL STANDARD

A. Legal Standards For The Admissibility Of Expert Causation Opinions

The PSC incorporates the *Plaintiffs' Steering Committee's Memorandum of Law Regarding the Rule 702 Standard ("Rule 702 Standard Brief")* (ECF 32994) and highlights the following points of particular relevance to the Court's consideration of this motion:

First, Fed. R. Evid. 702 has "a liberal policy of admissibility."[3] Exclusion of expert testimony is only appropriate when such testimony qualifies as irrelevant or "junk science"[4] Otherwise, the trial court should cede complex issues to the jury and rely on the traditional safeguards of the adversary system—active cross-examination, presentation of contrary and competing expert testimony—rather than

[2] McDonald SA, Fan Y, Welch WR, Cramer DW, Stearns RC, Sheedy, LJ, Katler, M, Godleski JJ. *Correlative polarizing light and scanning electron microscopy for the assessment of talc in pelvic region lymph nodes*. Ultrastructural Pathology 2019;43(1):13-27; Campion A, Smith KJ, Fedulov AV, Gregory DZ, Fan Y, Godleski JJ. *Identification of Foreign Particles in Human Tissues Using Raman Microscopy Analytical Chemistry* 2018 *90* (14), 8362- 8369; McDonald SA, Fan Y, Rogers RA, Godleski JJ. *Magnesium/silicon atomic weight percent ratio standards for the tissue identification of talc by scanning electron microscopy and energy dispersive X-ray analysis*, Ultrastructural Pathology, 2019; 43(6):248-260; *see* Exhibit 5 for additional publications on these topics.

[3] *Geiss v. Target Corp.*, 2013 WL 4675377, at *4 (D.N.J. Aug. 30, 2013) (citing, *inter alia, Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008).

[4] *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 596, 113 S. Ct. 2786 (1993).

exclude from juror scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies.[5]

Second, differing and competing expert opinions, precisely what Defendants have presented to the Court, are traditionally left for the jury. The *Daubert* analysis focuses on the methodology underlying an expert's opinion, not the expert's conclusions.[6] Therefore, the focus of admissibility under *Daubert* is the reliability of the experts' methods, not their correctness.[7] The trial court is not empowered "to determine which of several competing scientific theories has the best province."[8] As long as the expert's testimony falls within "the range where experts may reasonably differ," then it is up to the jury to decide among the competing views.[9]

Third, causal inference is a matter of judgment about the totality of the scientific evidence. "Drawing causal inference . . . requires judgment and searching analysis based on biology, of why a factor or factors may be absent despite a causal

[5] *In re TMI Litig.*, 193 F.3d 613, 692 (3d Cir. 1999) (amended on other grounds).
[6] *Daubert*, 509 U.S at 595.
[7] *Id*. at 585. *See also Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 1969 (1988); Fed. R. Evid. 702.
[8] *Milward v. Acuity Specialty Prod. Grp., Inc.*, 639 F.3d 11, 15 (1st Cir. 2011) (internal quotation marks and citations omitted).
[9] *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 153, 119 S. Ct. 1167 (1999); *In re: Tylenol (Acetaminophen) Mktg., Sales Practices, & Prod. Liab. Litig.*, 2016 WL 4039286, at *2 (E.D. Pa. July 28, 2016) ("Fed. R. Evid. 702 and *Daubert* put their faith in an adversary system designed to expose flawed expertise."); *United States v. Mitchell*, 365 F.3d 215, 244–45 (3d Cir. 2004) (citations omitted) ("As long as an expert's scientific testimony rests upon 'good grounds, based on what is known,' it should be tested by the adversary process— competing expert testimony and active cross–examination . . . .").

relationship, and vice versa."[10] As noted in the *Reference Manual on Scientific Evidence*: "Although the drawing of causal inference is informed by scientific expertise, it is not a determination that is made by using an algorithmic methodology."[11] As this judgment is a scientific determination, it can evolve "as new evidence develops" because "the scientific enterprise must always remain open to reassessing the validity of past judgments."[12] The judgment of whether to draw a causal inference can lead to disagreement amongst experts in the field.[13] In the end, deciding whether associations are causal typically is not a matter of statistics alone, but also rests on scientific judgment."[14] Defendants' brief is silent on this essential point.

Fourth, a causal inference requires an examination of the totality of the scientific evidence. "Scientific inference typically requires consideration of numerous findings, which, when considered alone, may not individually prove the contention."[15] This is how science outside of the courtroom functions. There is

[10] *Reference Manual on Scientific Evidence*, Federal Judicial Center, Third Edition (2011) ("Ref. Man.") at 600.
[11] *Id.*
[12] *Id.* at 598.
[13] *See, e.g., In re Neurontin Marketing, Sales Practices, and Products Liability Litigation,* 612 F. Supp. 2d 116, 149 (D. Mass. 2009) (causation supported by biologic plausibility notwithstanding the "robust debate in the scientific community" regarding the proposed mechanism); *Milward*, 639 F.3d at 18; *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig.*, 174 F. Supp. 3d 911 (D.S.C. 2016); *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, 2017 WL 1833173, at *9 (N.D. Ill. May 8, 2017).
[14] *Ref. Man.* at 20, 21, 222, 553, 565, 591, 599 and 600.
[15] *Id.* at 19–20; *see also Milward*, 639 F.3d at 26 (reversing the district court's exclusion of expert testimony based on an assessment of the contribution of individual studies and finding that the

simply no definitive checklist or magic formula for making scientific judgments. As explained in the *Reference Manual*:

> It appears that many of the most well-respected and prestigious scientific bodies (such as the International Agency for Research on Cancer (IARC), the Institute of Medicine, the National Research Council, and the National Institute for Environmental Health Sciences) consider all the relevant available scientific evidence, taken as a whole, to determine which conclusion or hypothesis regarding a causal claim is best supported by the body of evidence. In applying the scientific method, scientists do not review each scientific study individually for whether by itself it reliably supports the causal claim being advocated or opposed.[16]

As have numerous other courts, the Third Circuit has endorsed an expert's use of the "weight of the evidence" approach to assessing the "totality" of evidence for evaluating causation.[17]

Fifth, science does not demand certainty. Nor does the law. Under Third Circuit *Daubert* standards, the trial court should not impose "a standard of scientific certainty . . . beyond that which *Daubert* envisions."[18] Plaintiffs also are not required to present evidence that is conclusive or unequivocal. Science and medicine often do

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"weight of the evidence" properly supported the expert's opinion).

[16] *Ref. Man.* at 600.

[17] *See In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, 858 F.3d 787, 796– 797 (3d Cir. 2017) (citing *Milward*, 639 F.3d at 17 ("[t]he court treated the separate evidentiary components of [the expert's] analysis atomistically, as though his ultimate opinion was independently supported by each."); *see also Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 607 (D.N.J. 2002); *In re Tylenol (Acetaminophen) Mktg., Sales Practices, & Prod. Liab. Litig.*, 198 F. Supp. 3d 446, 458 (E.D. Pa. 2016); *In re Phenylpropanolamine (PPA) Prod. Liab. Litig.*, 289 F. Supp. 2d 1230, 1242 (W.D. Wash. 2003) (rejecting defense *Daubert* challenges which "isolate these sources [of evidence] rather than considering the whole").

[18] *Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co.*, 161 F.3d 77, 86 (1st Cir. 1998).

not lead to certainty and the law does not require certainty.[19] Again, Federal Rule of Evidence 702 has "a liberal policy of admissibility."[20]

B. Defendants' Motion Improperly Requests That the Court Weigh The Evidence On The Relationship Between Talcum Powder Products And Ovarian Cancer

In the context of a *Daubert* motion, the question before the Court is not whether the movant's experts or the respondent's experts are correct, or even what conclusion the Court would come to if it were the trier of fact. The sole question is whether each challenged expert used a reliable methodology.[21] Defendants' motion nevertheless attempts to convince the Court that they are "right" while disguising their arguments as a methodological challenge.

V. DEFENDANTS' ARGUMENTS

A. Defendants' Criticisms of Dr. Godleski's Pathology and Microscopy Methodologies are Misplaced and Based on Inaccurate Statements of Fact.

To support their arguments for excluding Dr. Godleski's opinions, Defendants misconstrue portions of Dr. Godleski's methods. For example, on page 3 of their

[19] *Milward*, 639 F.3d at 22 (quoting *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010)).
[20] *Geiss*, 2013 WL 4675377, at *4.
[21] *See, In re Testosterone Replacement Therapy Products Liability Litigation Coordinated Pretrial Proceedings*, 2017 WL 1833173, at *9 ("At this stage, it is not the Court's role to choose between competing studies…the studies "merits and demerits…can be explored at trial.") (citation omitted); *In re Roundup Prod. Liab. Litig.*, 2018 WL 3368534, at *2–3 (N.D. Cal. July 10, 2018) ("So long as an opinion is premised on reliable scientific principles, it should not be excluded by the trial judge; instead the weaknesses in an unpersuasive expert opinion can be exposed at trial, through cross examination or testimony by opposing experts").

Memorandum, Defendants state, "Dr. Godleski then reviewed the slides using scanning electron microscopy and energy dispersive X-ray analyses to observe the foreign material and identify any particles that he believed were talc." (Defendant's Memorandum pp. 3-4) This is simply wrong. Dr. Godleski did not study the surgical slides with SEM. He studied the whole tissue blocks, as described above, so as to observe particles and fibers *in situ,* and ensure the particles are not surface level, artifactual contamination.

Defendants' failure to distinguish between studying slides and blocks is exacerbated by their conflating of SEM atomic ratio determinations and the presence of birefringent particles in the surgical slides. Defendants acknowledge the well-accepted anatomic weight percent variance of +/- 5% of magnesium and silicon in talc, but then attempt to apply it to an unrelated statement that Dr. Godleski "cannot be certain whether the birefringent particulate matter he identified as being consistent with talc was not some other substance." (Defendants Memorandum, p. 4) Defendants' assertion is nonsensical and lacks context because Dr. Godleski does not attempt to ascertain the atomic composition of birefringent materials in the slides. Again, the determination of the atomic weigh percentages of particular particles is specific to studying tissue blocks by SEM/EDX, not studying slides with polarized light. Dr. Godleski clearly describes his methods in every expert report.

Moreover, Dr. Godleski is *quite certain* in his identification of talc and

asbestos using SEM/EDX. Dr. Godleski testified: "Q. With regard to what we're looking at in Figure 1, as we have discussed in the past with regard to polarized light microscopy, you cannot tell by this view what these birefringent particles are; correct? A. That's right. You can - -we can tell with certainty by electron microscopy." *See* Dr. Godleski Dep. 157:23-158:4, attached as **Exhibit 11.** Defendants' deliberate attempt to create an appearance of uncertainty by misconstruing Dr. Godleski's testimony in this way is misleading and should be rejected.

B. Defendants Also Misconstrue Dr. Godleski's Opinions as to a Causal Relationship Between the Presence of Talc and Asbestos in Plaintiffs' Tissue and Their Ovarian Cancer.

Despite unsuccessful attempts in all 14 trials to date, Defendants seek to exclude a statement from the very last paragraph of Dr. Godleski's reports wherein he concludes, "Therefore, based on the findings in this case, it can be stated to a reasonable degree of medical certainty, that the talc [and asbestos] found [in Plaintiffs' tissues] is contributory evidence for a causal link between the presence of talc [and asbestos] and the development of this patient's ovarian cancer." (Exhibits 6-10) In an effort to exclude this statement, Defendants take liberties with this statement well beyond that which Dr. Godleski intended. In its *proper* context, this statement (and other statements very similar to it) is scientifically accurate and fully

supported by the evidence, and it has been permitted in all 14 trials in which it has been offered.

To be clear, this statement is not offered as a complete opinion on causation. Rather, it is a carefully worded statement intended only to *support* the causation opinions of Plaintiffs' general causation and case specific experts. Obviously, the presence of talc and asbestos in Plaintiffs' ovaries or ovarian tumor supports the Plaintiffs' contention that talc and/or asbestos contributed to cause her ovarian cancer. It is the smoking gun found at the crime scene. But *how* the talc exposure contributes to cause ovarian cancer in general (and contributed to cause Plaintiffs' ovarian cancer specifically) will be explained by other experts. Dr. Godleski's opinion is merely that the presence of talc and asbestos in the tissue offers "contributory evidence" – that is, one piece of evidence that contributes to the overall causation analysis. The evidence is simply one contributory link in the causation chain that will be completed by other experts, which will likely include the testimony of experts in toxicology, epidemiology, cell biology, and gynecologic oncology.

As stated above, a causal inference requires an examination of the totality of the scientific evidence. "Scientific inference typically requires consideration of numerous findings, which, when considered alone, may not individually prove the contention."[22] At least forty epidemiology studies demonstrate a statistically

[22] *Ref. Man* at 19–20; *see also Milward*, 639 F.3d at 26 (reversing the district court's exclusion of

significant association between genital talc use and ovarian cancer. Numerous cell studies and toxicology studies demonstrate inflammation and neoplastic changes in epithelial cells exposed to talc. Other studies demonstrate talc can migrate from the vagina to the ovaries. Dr. Godleski's findings are just one piece of the causation puzzle, that when viewed in its totality, *support* causation. Plaintiffs do not contend Dr. Godleski's contributory evidence opinion standing alone proves causation.

Defendants also attempt to raise the *Daubert* bar to a level not required by Third Circuit precedent by suggesting that Dr. Godleski must prove the amount of talc necessary to cause cancer before his contribution opinion is admissible. This is simply not the law. Again, Dr. Godleski's opinions are not offered to establish complete causation. He is merely offering an opinion that the presence of talc and asbestos (the alleged causative offenders) in gynecologic tissue and in or near the tumor *supports* Plaintiffs' contention that talc and asbestos contributed to cause Plaintiffs' ovarian cancer.

Defendants also suggest Dr. Godleski's opinion regarding the presence of talc and asbestos and their contribution to the causation analysis is inadmissible because he never considered the possibility that other foreign particles caused Plaintiffs' ovarian cancer. This is not true. There is no requirement for Dr. Godleski to perform

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expert testimony based on an assessment of the contribution of individual studies and finding that the "weight of the evidence" properly supported the expert's opinion).

any type of differential diagnosis to offer just one piece of the larger causation puzzle. For certain, had Dr. Godleski observed the presence of some other carcinogen in Plaintiffs' tissue, he would have included that information in his reports. He did not. But the limited opinion offered by Dr. Godleski about the presence of talc (a probable human carcinogen according to the International Agency for Research on Cancer) and asbestos (a known and universally accepted human carcinogen), requires no differential diagnosis or exclusion of any other unobserved possible carcinogens. Defendants' arguments target the weight of the evidence offered, but do not adequately refute its admissibility. Experts are permitted to make reasonable inferences about the evidence, such as the presence of talc and asbestos in and around the ovary of a woman with ovarian cancer following decades of genital talc applications supports a causal connection. This is also information that can be considered and relied on by other Plaintiffs' experts when offering opinions that the genital use of talcum powder contributed to cause Plaintiffs' ovarian cancer.

Lastly, implausibly, Defendants argue that Dr. Godleski's partial causation opinion is inadmissible because he cannot state with certainty that the talc he found in Plaintiffs' tissue was specifically Johnson & Johnson's talc. Using his expertise and sound methodology, Dr. Godleski offers the opinion to a reasonable degree of medical certainty that the particles that he identified are talc or asbestos. While it is true the microscopic particles and fibers of talc and asbestos minerals are

not stamped with J&J's logo, the origin or source of the talc is for the jury to decide. Defendants appear to be making a relevance argument as to Dr. Godleski's observations of talc in the tissue. The relevance of such evidence is obvious. First, J&J experts claim talc cannot migrate from the vagina to the ovaries. Dr. Godleski's findings prove that assertion is untrue. Second, Plaintiffs will offer testimony of their long-term, frequent use of Defendants' products. The presence of talc in Plaintiffs' gynecologic tissue supports each Plaintiffs' testimony of usage and genital application. And, as previously stated, the presence of talc (and asbestos) on or adjacent to the ovaries, when considered alongside the other evidence-based opinions of other experts, supports causation. The jury must determine, based on the totality of the evidence, whether the talc and asbestos Dr. Godleski found more likely than not came from J&J's talcum powder products. Defendants' arguments may make for cross examination fodder, but they are not adequate to exclude Dr. Godleski's opinions.

VI. CONCLUSION

For these reasons, Defendants' motion to exclude Dr. Godleski's case-specific opinions should be denied.

Respectfully submitted,

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